

March 16, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar,

Thank you for your appearance and testimony last month before the Labor, Health and Human Service, and Education Appropriations Subcommittee. I wanted to follow-up on some of your comments regarding the liver allocation decision made last year that we discussed at the hearing.

As Secretary of the Department of Health and Human Services (HHS), one of your significant responsibilities is directing the United Network for Organ Sharing (UNOS), the federal contractor that administers the Organ Procurement and Transplantation Network (OPTN). In conjunction with your Department, UNOS develops the national organ allocation policies on which thousands of lives depend.

As we discussed at the hearing, last month, UNOS implemented what I believe to be a shortsighted and ill-conceived new liver allocation policy. UNOS did so despite a pending court challenge brought by more than a dozen of the country's leading hospitals and academic transplant centers. UNOS also did so despite findings by the federal judge hearing the challenge that UNOS's handling of the policy change created, "profound issues and institutional disruption." The judge also referred to evidence in the case's sealed record of UNOS's regional bias.

At the center of my concern is the impact the policy is already having on access to life-saving care, particularly in the Midwest and the South. As I wrote to UNOS's CEO Brian Shepard this past week, how are transplant programs in rural America supposed to stay afloat or retain top talent if the number of transplants in their region go down by 30 to 40 percent? In Missouri alone, transplants may decline by up to 32 percent.

In January, Senator Moran and I sent you a letter urging you to step in to prevent the implementation of this liver policy. As we outlined in our letter, and I reiterated at the hearing, the policy was expected to and has already caused considerable harm to patients and the system

by artificially reducing organ availability across large, mostly rural areas of the country while increasing transplant costs and organ waste.


In response to my questions about this policy at the hearing, you testified that HHS has requested UNOS to reconsider its decision to implement the policy. This sounds like a promising development, and I ask that you please provide further detail and documentation as to the nature and timing of HHS's request for such reconsideration, as well as the response from UNOS.

Further, you also testified that HHS does not make decisions on organ allocation policy and, by statute, has been "walled off" from doing so. I am very concerned by this statement as it contradicts my understanding of the National Organ Transplant Act and the Final Rule that governs HHS's authority to administer its provisions. Under the Final Rule, HHS has the authority to direct UNOS to revise organ allocation policies and, in this case, HHS exercised that authority to specifically direct the new liver policy's development and adoption. The Department has acknowledged that authority and specific direction in the lawsuit. In fact, hospitals located in large urban areas that lobbied for the new policy specifically credit your personal leadership. That is recognized, for example, in the December 17, 2018, letter to you from the Greater New York Hospital Association. Given that the Department interceded the last time a lawsuit was filed in 2018, it is unclear why you now state that you cannot direct revisions of policy now. I would appreciate a written explanation on this point.

Finally, my last question at the hearing concerned the evidence of regional bias in UNOS's policy process referenced by the federal judge. It is troubling that a federal contractor tasked with developing national organ allocation policies may be swayed by a regional bias. Unfortunately, this evidence is currently under seal, but my understanding is that the sealed documents have been made available to HHS in the course of the litigation. Have you been briefed on their contents? What are you doing to make this evidence publicly available and hold the contractor accountable? In my letter to UNOS CEO Shepard earlier this month, I asked him to provide the documents under seal to the Subcommittee and to make the information publicly available on UNOS's website. I have not yet received a response.

Thank you for again for your testimony on this important issue. Given the urgency of these matters, I would appreciate a response to these follow-up questions in the next two weeks.

Sincere regards,



Roy Blunt